NOV 5 2002

510(k) Summary of Safety and Effectiveness as Required by 21 CFR 807.92

Submitter	**Name:** Alfa Scientific Designs, Inc. **Address:** 12330 Stowe Drive Poway, CA 92064 Telephone: (858) 513-3888 Fax: (858) 513-8388 **Contact Person:** Naishu Wang, MD, Ph.D. **E-mail:** wnss@alfascientific.com
Device Name	**Trade Name:** *Instant-View ™LH Ovulation Predicting Test* **Common Name:** Luteinizing Hormone Test. **Classification:** Luteinizing Hormone Test System (21 CFR 862.1485) Class I
Date of Summary Preparation	October 9, 2002
Predicate Device	CLEARPLAN Easy™ One-Step Ovulation Predictor (K981271)
Device Description	This test is a one-step lateral flow chromatographic immunoassay.
Summary of the Similarity to the Predicate Device	• The intended use and performance characteristics: Both devices are intended to use for a detection of hLH surge in human urine. • Technological characteristics: Both devices are one step, qualitative, visual lateral flow immuno-Chromatographic test in a sandwich complex format. • Interpretation of results: The presence of C line serves as an internal quality control, and the presence of the T line indicates a positive result.

Intended Use	The *Instant-View™ LH Ovulation Predicting Test* is a qualitative immunoassay for the detection of human Luteinizing Hormone (hLH) in human urine to predict the occurrence of ovulation. This device is intended for professional and laboratory use only.
Performance Characters	The sensitivity of the device is 20mIU hLH/ml (WHO standards, LH 1st IRP 68/40). The correlation between the ***Instant-View ™ Ovulation Predicting Test*** and the legally marketed test compared is 99%. The negative results agreed 97.4% (37/38). The positive results agreed 100% (62/62). The reproducibility of this device was studied at three Physician's Office Laboratories (POL) and one reference laboratory. Evaluations were performed by personnel with diverse educational backgrounds and working experiences. Only one discrepancy was observed, that was within the range of 25% below the cutoff, and all other results obtained were as expected. The results from the four evaluation sites agreed 97.5%, indicating a high reproducibility of the device.
Two formats of the device, Dip-Strip and Cassette Test	Instant-View™ LH Ovulation Predicting Test has two formats, cassette test and dip-strip test. The cassette test contains the dip-strip in a plastic housing. Comparison studies between the two formats demonstrated that there is no difference in the performance of the cassette test and dip-strip test.
Conclusion	These results demonstrate that the *Instant-View™ LH Ovulation Predicting Test*, in the format of cassette and dip-strip, is substantially equivalent to the legally marketed test.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 5 2002

Naishu Wang, M.D., Ph.D.
President
Alfa Scientific Designs, Inc.
12330 Stowe Drive
Poway, CA 92064

Re: k022829
Trade/Device Name: *Instant-View*™ LH Ovulation Predicting Test
Regulation Number: 21 CFR 862.1485
Regulation Name: Luteinizing Hormone Test System
Regulatory Class: Class I
Product Code: CEP
Dated: August 21, 2002
Received: August 26, 2002

Dear Dr. Wang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(K) NUMBER (IF KNOWN): **K022829**

DEVICE NAME: *Instant-View™* LH Ovulation Predicting Test

INDICATIONS FOR USE:

The *Instant-View™ LH Ovulation Predicting Test* is a qualitative immunoassay for the detection of human Luteinizing Hormone (hLH) in human urine to predict the occurrence of ovulation. It is for health care professional use, including at the point of care (physician's office labs, doctor's offices).

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K022829

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)